K063587

510(k) Summary

JAN - 9 2007

510(k) Owner: Xodus Medical, Inc.
Westmoreland Business & Research Park
702 Prominence Drive
New Kensington, PA 15068
Phone: 724-337-5500
Fax: 724-337-0555
Contact: Brenda Niel (Quality Assurance Manager)

Establishment Registration Number: 2530138

Date Prepared: November 28, 2006

Device Information

Trade/Device Name: Anti-Fog Solution
Common Name: Anti-Fog Solution
Classification Name: Endoscope And/ Or Accessories
Regulation Number: 21 CFR 876.1500
Product Code: KOG
Regulatory Class: II

Predicate Device

Device Name: Clear it Anti-Fog
Common Name: Anti-Fog Solution
510 (k) Number: K022826
510 (k) Owner: Preservation Solutions, Inc.
Classification Name: Endoscope And/Or Accessories
Regulation Number: 21 CFR 876.1500
Product Code: KOG
Regulatory Class: II

510(k) Summary

Device Description

The Anti-Fog solution is a clear / colorless, odorless, water soluble solution comprised of predominantly water (≈95%) with small percentages of surfactant (<5%), isopropanol (<1%) and ethanol (<0.5%). Anti-fog solution functions by reducing the surface tension of water, thus preventing water droplets (fog) from forming on the lenses of endoscopic/ laparascopic instruments during use. This solution is bottled in a volume of 6cc's in a 10cc clear plastic dropper bottle according to approved manufacturing processes by an FDA registered establishment (See Appendix C). Included in the tyvek pouch packaging of this product is a 1 3/4" x 1 ½" adhesive backed, non-abrasive, x-ray detectable radiopaque, polyurethane foam pad for applying the product to endoscopic / laparascopic lenses. This product is sold sterile to healthcare professionals only.

Intended Use

Anti-Fog is intended to be used to prevent "fogging" (caused by condensation) on the lenses of endoscopic/laparascopic instruments which are likely to fog during use.

Technological Characteristics Comparison

Xodus Medical Inc.'s Anti-Fog kit has the same physical characteristics, chemical composition and packaging design as the predicate device Preservation Solutions, Inc.'s Clear it Anti-fog kit. Chemical composition and quantification for the Xodus Medical Anti-fog solution were determined by two separate deformulations performed on the Preservation Solutions Clear it anti-fog solution to ensure formula accuracy. Both the Preservation Solutions, Inc. and Xodus Medical's Anti-Fog are clear/colorless, odorless, water soluble solutions bottled in 10cc clear plastic dropper bottles and packaged in a tyvek pouch in conjunction with an adhesive backed, non-abrasive polyurethane foam pad containing an x-ray detectable radiopaque strip. Both the predicate device and Xodus Medicals' device are used to prevent fogging of endoscopic/laparascopic lenses during procedures.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Xodus Medical, Inc.
% Ms. Brenda Niel
Quality Assurance Manager
702 Prominence Drive
New Kensington, Pennsylvania 15068

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Re: K063587
Trade/Device Name: Anti-Fog Solution
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: KOG
Dated: November 28, 2006
Received: December 1, 2006

Dear Ms. Niel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

cc: HFZ-401 DMC

Indications for Use

510(k) Number (if known): K063587

Device Name: Anti-Fog Solution

Indications for Use:

Anti-Fog is intended to be used to prevent "fogging" caused by condensation on the lenses of endoscopic/laparascopic instruments which are likely to fog during use.

Prescription Use X (Per 21 CFR 801 Subpart D) OR Over-The Counter Use ___ (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of ~~Device Evaluation (ODE)~~

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K063587